

### REMARKS

Claims 1, 3, 9, 10, 12 and 13 were pending in this application/prior to the amendments herein. Claim 1 is amended herein. Claims 1, 3, 9, 10, 12 and 13 therefore remain pending.

#### Rejections under 35 U.S.C. § 112

Claims 1, 3, 9, 10, 12 and 13 were rejected under 35 U.S.C. § 112. The Office Action states that the Examiner has not been able to find a standard of roughness, which causes a problem with the claims and specification since there is no way to figure out the scope of the claims and how to determine the roughness of an element that is between No. 20 to 1500 as expressed in terms of counts of sand paper.

An article "Temporal code in the vibrissal system-Part II: Roughness surface discrimination," by Farfan et.al. that was published in the proceedings of the 16<sup>th</sup> Argentine Bioengineering Congress and the 5<sup>th</sup> Conference of Clinical Engineering, Journal of Physics: Conference Series (90), 2007 is submitted in the accompanying Information Disclosure Statement. In section 2.3 of this article the authors show that the roughness of a surface can be correlated to the roughness of sandpaper having a certain grit size by measuring the  $R_a$  parameter of the roughened surface.

As evidenced by the usage in the Farfan et al. article, a person skilled in the art would be able to measure the  $R_a$  parameter of a surface roughened by any technique and correlate it to the average roughness of the sandpaper having a certain grit size. As a result, Applicants believe that a person skilled in the art would be able to measure the roughness of the cross section of the roughened surface of the flange and correlate it to the roughness of the grades of sand paper recited in Claim 1. Applicants respectfully submit that the language disclosed in Claim 1 is sufficient to enable a person skilled in the art to make the injection apparatus commensurate in scope with the Claims 1, 3, 9, 10, 12 and 13.

Nevertheless, Applicants have amended Claim 1 to clarify that "...the cross section of the roughened surface has a roughness **equivalent to that** of about No. 20 to 1500 as expressed in terms of count of sand paper." (emphasis added). Applicant submits that a person skilled in the art would recognize that the roughness of the roughness is equivalent to the roughness of the recited grades of sandpaper.

In view of the foregoing, Applicants respectfully request the Examiner to withdraw rejections of Claims 1, 3, 9, 10, 12 and 13 under 35 U.S.C. § 112.

Rejections under 35 U.S.C. § 103(a)

The Office Action rejects Claims 1, 3, 9, 10, 12 and 13 as being unpatentable over U.S. Patent No. 5,407,431 by Botich et. al. in view of U.S. Publication No. 2001/0014996 A1 by Ericsson et. al. and U.S. Patent No. 4,804,368 by Skakoon et. al.

Without conceding the propriety of combining Botich with Ericsson and Skakoon, Applicants respectfully traverse this rejection on the basis that combining these references would not lead one having ordinary skill in the art to produce the presently claimed invention. The roughening of at least one of the front and rear surface of the flange recited in the presently pending claims is effective to prevent the breakage of the syringe when discharging liquid from a syringe or introducing liquid into a syringe. The grooves 83 on the front surface of the flange 79 disclosed in Botich are configured to provide greater co-efficient of friction between the fingers and the thumb. See for example, column 11, lines 17-24. Thus, the grooves of Botich are not equivalent to the roughness recited in the claims. Neither Ericsson nor Skakoon provide any suggestion at all of anything that might be construed as suggestion such roughness. Thus, the recited roughness is not suggested in any of the cited references.

The accompanying expert Declaration further establishes that the grooves are not equivalent to the recited surface roughness. As explained in the Declaration, the grooves on the syringe barrel disclosed by Botich would not provide any benefit in preventing breakage of the syringe when used with a cylinder holder with flange insertion groove. As a result, the combination of references cited by the Examiner simply would not provide any suggestion of the claimed invention having a surface with the recited reference. Accordingly, no proper *prima facie* showing of obviousness can be established by these references.

Furthermore, the ability to prevent breakage of the syringe when discharging liquid from a syringe or introducing liquid into a syringe is a significant unexpected result that would rebut any *prima facie* showing of obviousness, even were such a showing present. Nothing in the prior art would suggest that the recited roughness could increase resistance to breakage. Thus, it is clear that the increased resistance to breakage is a surprising and unexpected result of the presently claimed invention.

Moreover, the unexpectedness of this result is further evidenced by the data supplied in the specification at Table 2. As explained in the accompanying expert declaration, if the syringe barrel disclosed by Botich or that having a similar structure were tested in the manner described

in the present application, results similar to that obtained for the comparative examples having no roughened surfaces would be obtained. Thus, the data described in Table 2 of the present application in which roughened surfaces are compared with non-roughened surfaces further evidences the unexpectedness of the results obtained.

Therefore Claims 1, 3, 9, 10, 12 and 13 as presented above are patentable over Botich in view of Ericsson and Skakoon both because these references do not create a *prima facie* showing of obviousness, and because the unexpected results would rebut any *prima facie* showing even were such a showing present. Accordingly, Applicants respectfully request the Examiner to withdraw rejections to Claims 1, 3, 9, 10, 12 and 13 and allow them to issue.

### CONCLUSION

Applicants respectfully submit that all of the pending claims are allowable. Applicants respectfully request that the Examiner withdraw the rejections and pass Claims 1, 3, 9, 10, 12 and 13 to issuance. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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